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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,827	01/22/2002	Alastair J Wood	3051-29752	5772

7590 06/30/2003
Barnes & Thornburg
11 South Meridian Street
Indianapolis, IN 46204

EXAMINER

TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/031,827

Applicant(s)
Wood et al

Examiner
R.S. Travers J.D., Ph.D.

Art Unit
1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of the communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All ☐ Some ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) (Paper No.)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTD-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) (Paper No.) 3, 5 6) ☐ Other:

Art Unit:

Claims 1-22 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art

Art Unit:

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines those compounds suitable as "protease inhibitors" as envisioned for use in the instant invention. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of compounds suitable as "protease inhibitors" as envisioned for use in the instant invention examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all compounds suitable as "protease inhibitors" as envisioned for use in the instant invention, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-2, 5-15 and 18-22 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Art Unit:

Claims 1-2, 5-12, 13-15 and 18-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 5-15 and 18-22 are rendered indefinite by the phrase "protease inhibitors" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are "a functionally equivalent analog thereof" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed

Art Unit:

invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Kim et al, in view of Pfister et al.

Kim et al teach the claimed anti-retroviral compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These specific medicaments are taught as useful for treating HIV infections, and having their therapeutic efficiency compromised by P-glycoprotein mediated transport systems reducing medicament levels in target cells. Kim et al teach the inhibition of P-glycoprotein transport systems as facilitating the activity of anti-retroviral medicaments as herein claimed. Claims 1-22, and the primary reference, differ as to:

- 1) the concomitant employment of the claimed medicaments, and
- 2) administration of various methanodibenzosuberane compounds to inhibit a P-glycoprotein medicament transport system.

It is generally considered prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of an efficacious anti-retroviral therapeutic agent and conventional anti-P-

Art Unit:

glycoprotein inhibiting agents old and well known for increasing the concentrations of biocidal medicaments. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 1-22 require administration of a specific P-glycoprotein transport inhibitor for increasing the levels of medicament in target cells. Kim et al teach the use of P-Glycoprotein transport inhibitors as useful for ameliorating the reduced therapeutic efficacy caused by the P-glycoprotein transport system. Pfister et al teach the instant methanodibenzosuberane compounds as old and well known P-glycoprotein transport system inhibitors. Possessing the Kim et al teachings, the skilled artisan would have been instructed to employ P-glycoprotein transport inhibitors concomitantly with anti-retroviral agents thereby facilitating these antiviral agents activity. Pfister et al teaching the claimed methanodibenzosuberane compounds as old and well known P-glycoprotein transport inhibitors would have motivated the skilled artisan to employ these compounds to inhibit the P-glycoprotein system and enjoy a reasonable expectation of therapeutic success. Examiner notes the selection of one or another compound for a specific therapeutic purpose from that group of compounds known to possess the requisite therapeutic activity would have been seen as selection from obvious alternatives. Thus, the concomitant employment of the compounds herein claimed would have been seen as obvious to those of normal skill in the art.


No claims are allowed.

Application/Control Number: 10/031,827

Page 7

Art Unit:

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers
Primary Examiner
Art Unit 1617